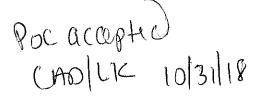
Bridgeport Hospital – 070010 Complaint #23680 Survey date: 7/26/2018



Page	Deficiency	Plan of Correction	Completion Date
3-5	1 a,b	As of midnight 10/20/18 cytopathology specimens including GYN and non-GYN are no longer being processed at Bridgeport Hospital. Specimen processing will be done at Yale School of Medicine. As of 5:00 pm 10/22/18 interpretation of slides was discontinued at Bridgeport Hospital. Bridgeport Hospital will still be performing adequacy assessment for Non-GYN FNAs on site. These will be reconfirmed at Yale School of Medicine.	10/22/18
		Bridgeport Hospital has developed a memorandum of understanding with Yale School of Medicine to process and read all GYN and non-GYN cytopathology specimens. As part of this process, Bridgeport Hospital will ensure the quality of service provided by Yale School of Medicine by having Bridgeport-based pathologists review 20 percent of specimen slides originating at Bridgeport Hospital and then processed and interpreted at Yale School of Medicine. Bridgeport Hospital will further audit time of accession to time of final result for specimens obtained from Bridgeport Hospital patients and processed at Yale School of Medicine to ensure continuity of service. Both of these metrics will be reported at the Laboratory Quality Committee. All results of specimens processed and read at Yale School of Medicine will be available for interpretation by ordering physicians at Bridgeport Hospital in the same manner as when specimens were processed at Bridgeport Hospital.	
		During specimen processing slides were switched and as a result of system and human error, physicians were provided with inaccurate information on which they based their treatment plans and informed consent for the two patients involved. The error was disclosed to the patients and practitioners involved and amended reports issued. Corrective actions included:	
		<ul> <li>The practice of processing both urine and GYN specimens on the same tray had been discontinued on 8/29/17. (Responsible: Laboratory Medical Director)</li> </ul>	
		<ul> <li>A double check process to verify placement of the tubes and slides by another staff member had been implemented on 8/29/17. (Responsible: Laboratory Administrative Manager)</li> </ul>	
		<ul> <li>A red dot/mark had been added as a visual cue on the side of all slide trays to indicate position one, the correct position to start loading racks had been implemented on 8/29/17. (Responsible: Laboratory Medical Director)</li> </ul>	
		<ul> <li>Cytology prep technician distraction while processing specimens:</li> <li>During processing, phone calls were forwarded to the administrative staff to screen calls and triage information. Completed on 8/30/17. (Responsible: Laboratory Administrative Manager)</li> </ul>	
		<ul> <li>Signage and a bin had been used to designate where to leave specimens when the cytology prep technician was processing specimens and was unavailable to take the specimens. Completed on 8/29/17. (Responsible: Laboratory Administrative Manager).</li> </ul>	

		<ul> <li>Interruptions: Throughout the hospital a STAR (stop-think-act-review) decal is used in front of the medication dispensing machines on the units to designate a "no interruption" zone while nurses are preparing medications. A similar concept had been implemented on 8/30/17 in the cytology lab by hanging a stop sign on the door to indicate when specimen processing was taking place and that the technician should not have been interrupted.</li> <li>The GYN using SurePath policy was revised to include all of the elements from the corrective action plan and was approved by the Laboratory Medical Director on 9/25/18.</li> <li>The plan of correction was presented at the Laboratory QA Committee on</li> </ul>	
		9/5/18 and at the hospital's Quality Council whose membership includes Sr Staff, hospital Chairmen and Directors on 9/13/18 and at the Professional and Quality Review Committee of the Board on 9/20/18.  Utilizing the SurePath protocol for processing urines was discontinued and the	
		process was reverted back to using the standard Cytospin process on 9/14/18.	
5-6	2 A,B	As of midnight 10/20/18 cytopathology specimens including GYN and non-GYN are no longer being processed at Bridgeport Hospital. Specimen processing will be done at Yale School of Medicine. As of 5:00 pm 10/22/18 interpretation of slides was discontinued at Bridgeport Hospital. Bridgeport Hospital will still be performing adequacy assessment for Non-GYN FNAs on site. These will be reconfirmed at Yale School of Medicine.	10/22/18
		Bridgeport Hospital has developed a memorandum of understanding with Yale School of Medicine to process and read all GYN and non-GYN cytopathology specimens. As part of this process, Bridgeport Hospital will ensure the quality of service provided by Yale School of Medicine by having Bridgeport-based pathologists review 20 percent of specimen slides originating at Bridgeport Hospital and then processed and interpreted at Yale School of Medicine. Bridgeport Hospital will further audit time of accession to time of final result for specimens obtained from Bridgeport Hospital patients and processed at Yale School of Medicine to ensure continuity of service. Both of these metrics will be reported at the Laboratory Quality Committee. All results of specimens processed and read at Yale School of Medicine will be available for interpretation by ordering physicians at Bridgeport Hospital in the same manner	
		as when specimens were processed at Bridgeport Hospital.	
		To ensure plans of correction are implemented and monitored for Lab events: At the Anatomic Pathology QA meeting of 9/5/18, the need for discussion and documentation of all QA issues involving the AP section of the Lab was emphasized. The standing agenda for the QA meeting has been modified to reflect the need to discuss nonconforming events as well as to follow-up on such occurrences. All nonconforming events are reported to the Lab Administrative manager who incorporates the issue into the "P" drive in the hospital network	

		for tracking. Nonconforming events policy has been revised to reflect this. The	
		minutes of the AP meeting will reflect discussion and follow-up on all	
		nonconforming events, action plans and retraining.	
		To ensure corrective action plans for all RCAs are implemented and monitored:	
		RCA corrective action plans for adverse events with related policies,	
		education plan and monitoring is reviewed by Performance	
		Management and a checklist used to monitor and ensure completion.	
		Completed 8/31/18. (responsible: V.P. Performance/Risk Management)	
		Monitoring of compliance is done through the service line/departments	
		Quality Committee (For the Laboratory the Lab Quality Committee is	
		responsible for this oversight as outlined in the "Management of	
		Nonconforming Events" policy. Completed 9/5/18. (responsible: Lab	
		Medical Director)	
		A Safety Event Management Policy was developed and outlines the	
		process for "Implementing and Monitoring Action Plans to Prevent	
		Reoccurrence". Per the policy the delivery network risk manager will	
		monitor corrective action plans and escalate concerns regarding	
		sustainability to the appropriate leader or leadership group. Completed	
		7/25/18.(responsible: Risk Management Specialist)	
		Adverse events are reported to the hospital's Quality Council whose  Adverse events are reported to the hospital's Quality Council whose  Adverse events are reported to the hospital's Quality Council whose	
		membership includes Sr Staff, hospital Chairmen (including Pathology)	
		and Directors and also to the Professional and Quality Review	
		Committee of the Board. Service lines and departments report	
		biannually.	
		The Laboratory provided a report at Quality Council on 8/13/18 and at	
		the Quality meeting of the Board on 9/20/18 which included an update	
		on the event and status of corrective actions and monitoring.	
		(Responsible: V.P. Ambulatory Services & Chairman of Pathology)	
6	2C	As of midnight 10/20/18 cytopathology specimens including GYN and non-GYN	10/22/18
		are no longer being processed at Bridgeport Hospital. Specimen processing will	
		be done at Yale School of Medicine. As of 5:00 pm 10/22/18 interpretation of	
		slides was discontinued at Bridgeport Hospital. Bridgeport Hospital will still be	<u> </u> 
		performing adequacy assessment for Non-GYN FNAs on site. These will be re-	
		confirmed at Yale School of Medicine.	-
		Bridgeport Hospital has developed a memorandum of understanding with Yale	
		School of Medicine to process and read all GYN and non-GYN cytopathology	
		specimens. As part of this process, Bridgeport Hospital will ensure the quality of	
		service provided by Yale School of Medicine by having Bridgeport-based	
		pathologists review 20 percent of specimen slides originating at Bridgeport	
		Hospital and then processed and interpreted at Yale School of Medicine.	
		Bridgeport Hospital will further audit time of accession to time of final result for	
		specimens obtained from Bridgeport Hospital patients and processed at Yale	
		School of Medicine to ensure continuity of service. Both of these metrics will be	
		reported at the Laboratory Quality Committee. All results of specimens	
		processed and read at Yale School of Medicine will be available for	
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	interpretation by ordering physicians at Bridgeport Hospital in the same manner as when specimens were processed at Bridgeport Hospital.  Subsequent revisions had also been made to the policy to ensure all of the processing steps were detailed for new hires to perform the procedure without undue difficulty. Policies had been reviewed by the Lab Medical Director and had been reviewed and signed off by the technical personnel who would be performing the procedures. The policies and procedures had been available in the cytology prep area and the technical personnel had been instructed to follow the procedure exactly as written (Responsible: Laboratory medical Director) In addition, the following processes have been put into place to ensure policies for all RCA corrective actions will be updated and revised accordingly:  RCA corrective action plans for adverse events with related policies, education plan and monitoring will be reviewed by Performance Management and a checklist used to monitor and ensure completion. Completed 8/31/18. (responsible: V.P. Performance/Risk Management)  A Safety Event Management Policy was developed and outlines the process for "Implementing and Monitoring Action Plans to Prevent Reoccurrence". Per the policy the delivery network risk manager will monitor corrective action plans and escalate concerns regarding sustainability to the appropriate leader or leadership group. Completed 7/25/18.(responsible: Risk Management Specialist)	
6-7 2D	As of midnight 10/20/18 cytopathology specimens including GYN and non-GYN are no longer being processed at Bridgeport Hospital. Specimen processing will be done at Yale School of Medicine. As of 5:00 pm 10/22/18 interpretation of slides was discontinued at Bridgeport Hospital. Bridgeport Hospital will still be performing adequacy assessment for Non-GYN FNAs on site. These will be reconfirmed at Yale School of Medicine.  Bridgeport Hospital has developed a memorandum of understanding with Yale School of Medicine to process and read all GYN and non-GYN cytopathology specimens. As part of this process, Bridgeport Hospital will ensure the quality of service provided by Yale School of Medicine by having Bridgeport-based pathologists review 20 percent of specimen slides originating at Bridgeport Hospital and then processed and interpreted at Yale School of Medicine. Bridgeport Hospital will further audit time of accession to time of final result for specimens obtained from Bridgeport Hospital patients and processed at Yale School of Medicine to ensure continuity of service. Both of these metrics will be reported at the Laboratory Quality Committee. All results of specimens processed and read at Yale School of Medicine will be available for interpretation by ordering physicians at Bridgeport Hospital in the same manner as when specimens were processed at Bridgeport Hospital.  The decision had been made to discontinue using the SurePath protocol for processing urines and the procedure had reverted back to using the standard Cytospin process.	10/22/18

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7	2E	As of midnight 10/20/18 cytopathology specimens including GYN and non-GYN	10/22/18
		are no longer being processed at Bridgeport Hospital. Specimen processing will	20,22,20
		be done at Yale School of Medicine. As of 5:00 pm 10/22/18 interpretation of	
		slides was discontinued at Bridgeport Hospital. Bridgeport Hospital will still be	
		performing adequacy assessment for Non-GYN FNAs on site. These will be re-	
		confirmed at Yale School of Medicine.	
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		Bridgeport Hospital has developed a memorandum of understanding with Yale	
		School of Medicine to process and read all GYN and non-GYN cytopathology	
		specimens. As part of this process, Bridgeport Hospital will ensure the quality of	
		service provided by Yale School of Medicine by having Bridgeport-based	
		pathologists review 20 percent of specimen slides originating at Bridgeport	
		Hospital and then processed and interpreted at Yale School of Medicine.	
		Bridgeport Hospital will further audit time of accession to time of final result for	
1		specimens obtained from Bridgeport Hospital patients and processed at Yale	
		School of Medicine to ensure continuity of service. Both of these metrics will be	
		reported at the Laboratory Quality Committee. All results of specimens	
		processed and read at Yale School of Medicine will be available for	
		interpretation by ordering physicians at Bridgeport Hospital in the same manner	
		as when specimens were processed at Bridgeport Hospital.	
		as when specimens were processed at bridgeport hospital.	
		Staff education is completed by just in time training with a sign in	
		sheet used to document completion. A record of all training will be	
		maintained by the Laboratory Administrative Manager.	
		(Responsible: Laboratory Administrative Manager)	
		(Nesponsione: Edisoratory Frammistrative Manager)	
		The following processes have been put into place to ensure a plan for education	
		for all RCA corrective actions is addressed:	
		RCA corrective action plans for adverse events with plan for education	
		will be reviewed by Performance Management to ensure education has	
		been appropriately addressed. Completed 8/31/18. (responsible: V.P.	
		Performance/Risk Management)	
		A Safety Event Management Policy was developed and outlines the	
		process for "Implementing and Monitoring Action Plans to Prevent	
		Reoccurrence". Per the policy the delivery network risk manager will	
		monitor corrective action plans and escalate concerns regarding	
		sustainability to the appropriate leader or leadership group. Completed	
		7/25/18.(responsible: Risk Management Specialist)	

7	2E(a)	The corrective action plans that had been put into place to address distractions (i.e. STOP sign and process for dropping off specimens) were outlined in an SBAR formatted document that was used for re-education and distributed via e-mail on 8/17/18.	
		In addition to the SBAR, all five cytology personnel had been re-educated by policy review with sign off. (Responsible: Laboratory Medical Director)	10/22/18
7	2E(b)	Administrative staff, in addition to the SBAR had been also re-educated via email on 8/17/18 with a request to respond as acknowledgement on the need to screen phone calls and triage information for the cytology prep technicians when they were processing specimens. (Responsible: Laboratory Administrative Manager)	
		Central Processing staff had been re-educated via the SBAR with review and sign-off was completed by 9/5/18. (Responsible: Laboratory Administrative Manager)	10/22/18
		All Laboratory staff had been re-educated via SBAR e-mail on 8/17/18 and topic had been also addressed at the Laboratory Staff meeting on 8/29/18.(Responsible: Laboratory Administrative Manager)	
		In addition, the SBAR e-mail was sent on 8/17/18 to hospital leadership staff to address with hospital staff that might also drop off specimens to cytology. (Responsible: Laboratory Administrative Manager)	
7	2F	As of midnight 10/20/18 cytopathology specimens including GYN and non-GYN are no longer being processed at Bridgeport Hospital. Specimen processing will be done at Yale School of Medicine. As of 5:00 pm 10/22/18 interpretation of slides was discontinued at Bridgeport Hospital. Bridgeport Hospital will still be performing adequacy assessment for Non-GYN FNAs on site. These will be reconfirmed at Yale School of Medicine.	10/22/18
		Bridgeport Hospital has developed a memorandum of understanding with Yale School of Medicine to process and read all GYN and non-GYN cytopathology specimens. As part of this process, Bridgeport Hospital will ensure the quality of service provided by Yale School of Medicine by having Bridgeport-based pathologists review 20 percent of specimen slides originating at Bridgeport Hospital and then processed and interpreted at Yale School of Medicine.	
		Bridgeport Hospital will further audit time of accession to time of final result for specimens obtained from Bridgeport Hospital patients and processed at Yale School of Medicine to ensure continuity of service. Both of these metrics will be reported at the Laboratory Quality Committee. All results of specimens processed and read at Yale School of Medicine will be available for	
		interpretation by ordering physicians at Bridgeport Hospital in the same manner as when specimens were processed at Bridgeport Hospital.	
		The Urine Cytology Prep using SurePath policy was initially revised to include all of the elements from the corrective action plan updates	

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8	2H	As of midnight 10/20/18 cytopathology specimens including GYN and non-GYN are no longer being processed at Bridgeport Hospital. Specimen processing will be done at Yale School of Medicine. As of 5:00 pm 10/22/18 interpretation of	10/22/18
		To ensure that events and corrective actions are appropriately discussed and recorded at the Laboratory Quality Assurance Committee, the "Management of Nonconforming Events" policy was revised on 8/21/18 to include the following: "Standing agenda items at all QA meetings include: review of all nonconforming events as well as follow-up discussion in the following meeting as to updates, training and monitoring. All of this will be documented in the appropriate Quality Assurance meeting minutes." Education on the policy took place at the Quality Assurance Committee meeting on September 5, 2018. (Responsible: Laboratory Medical Director/Committee Chairman.)	-
		Bridgeport Hospital has developed a memorandum of understanding with Yale School of Medicine to process and read all GYN and non-GYN cytopathology specimens. As part of this process, Bridgeport Hospital will ensure the quality of service provided by Yale School of Medicine by having Bridgeport-based pathologists review 20 percent of specimen slides originating at Bridgeport Hospital and then processed and interpreted at Yale School of Medicine. Bridgeport Hospital will further audit time of accession to time of final result for specimens obtained from Bridgeport Hospital patients and processed at Yale School of Medicine to ensure continuity of service. Both of these metrics will be reported at the Laboratory Quality Committee. All results of specimens processed and read at Yale School of Medicine will be available for interpretation by ordering physicians at Bridgeport Hospital in the same manner as when specimens were processed at Bridgeport Hospital. Bridgeport Hospital will still be performing adequacy assessment for Non-GYN FNAs on site. These will be re-confirmed at Yale School of Medicine.	
7-8	2G	procedure had reverted back to using the standard Cytospin process on 9/14/18.  The Document Control System Policy notes that "all procedural changes must be reviewed and signed by the Medical Director and reviewed by staff before becoming Standard Operating Procedure". Staff had been re-educated on the policy at the Laboratory Staff meeting on 8/29/18. (Responsible: Administrative Manager)  As of midnight 10/20/18 cytopathology specimens including GYN and non-GYN are no longer being processed at Bridgeport Hospital. Specimen processing will be done at Yale School of Medicine. As of 5:00 pm 10/22/18 interpretation of	10/22/18
		completed on 7/31/18 with policy approval by the Laboratory Medical Director.  Subsequent to the policy changes referenced above the decision had been made to discontinue using the SurePath protocol for processing urines and the	

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	slides was discontinued at Bridgeport Hospital. Bridgeport Hospital will still be performing adequacy assessment for Non-GYN FNAs on site. These will be re-	
	confirmed at Yale School of Medicine.	
	Bridgeport Hospital has developed a memorandum of understanding with Yale School of Medicine to process and read all GYN and non-GYN cytopathology specimens. As part of this process, Bridgeport Hospital will ensure the quality of service provided by Yale School of Medicine by having Bridgeport-based pathologists review 20 percent of specimen slides originating at Bridgeport Hospital and then processed and interpreted at Yale School of Medicine. Bridgeport Hospital will further audit time of accession to time of final result for specimens obtained from Bridgeport Hospital patients and processed at Yale School of Medicine to ensure continuity of service. Both of these metrics will be reported at the Laboratory Quality Committee. All results of specimens processed and read at Yale School of Medicine will be available for interpretation by ordering physicians at Bridgeport Hospital in the same manner as when specimens were processed at Bridgeport Hospital.	
	The Cytology prep technicians with the revised form have had competency completed again by a Pathologist qualified under CLIA as a cytology technician supervisor before performing processing.  In addition, the elements have also been added to the new employee training checklist. (Responsible: Laboratory Medical Director)	
8 21	As of midnight 10/20/18 cytopathology specimens including GYN and non-GYN are no longer being processed at Bridgeport Hospital. Specimen processing will be done at Yale School of Medicine. As of 5:00 pm 10/22/18 interpretation of slides was discontinued at Bridgeport Hospital. Bridgeport Hospital will still be performing adequacy assessment for Non-GYN FNAs on site. These will be reconfirmed at Yale School of Medicine.	10/22/18
	Bridgeport Hospital has developed a memorandum of understanding with Yale School of Medicine to process and read all GYN and non-GYN cytopathology specimens. As part of this process, Bridgeport Hospital will ensure the quality of service provided by Yale School of Medicine by having Bridgeport-based pathologists review 20 percent of specimen slides originating at Bridgeport Hospital and then processed and interpreted at Yale School of Medicine.	
	Bridgeport Hospital will further audit time of accession to time of final result for specimens obtained from Bridgeport Hospital patients and processed at Yale School of Medicine to ensure continuity of service. Both of these metrics will be reported at the Laboratory Quality Committee. All results of specimens	
	processed and read at Yale School of Medicine will be available for interpretation by ordering physicians at Bridgeport Hospital in the same manner as when specimens were processed at Bridgeport Hospital.	
	The Quality Assurance Program for Gynecologic Cytology addressed preanalytical quality assessment under section "XI. Recording of	

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		Specimens". To be more comprehensive and in better sequential order a new section had been added with the heading of "Preanalytic Quality Assessment" to better address this topic. Education on the policy was provided at the Lab Quality Assurance Committee meeting on September 5, 2018. Preanalytic quality assessment is also addressed in the Anatomic Pathology Quality Assurance Program. (Responsible: Laboratory Medical Director)	
		Revisions to be more comprehensive have been made to both QA plans.	
8	2J	As of midnight 10/20/18 cytopathology specimens including GYN and non-GYN are no longer being processed at Bridgeport Hospital. Specimen processing will be done at Yale School of Medicine. As of 5:00 pm 10/22/18 interpretation of slides was discontinued at Bridgeport Hospital. Bridgeport Hospital will still be performing adequacy assessment for Non-GYN FNAs on site. These will be reconfirmed at Yale School of Medicine.	10/22/18
		Bridgeport Hospital has developed a memorandum of understanding with Yale School of Medicine to process and read all GYN and non-GYN cytopathology specimens. As part of this process, Bridgeport Hospital will ensure the quality of service provided by Yale School of Medicine by having Bridgeport-based pathologists review 20 percent of specimen slides originating at Bridgeport Hospital and then processed and interpreted at Yale School of Medicine. Bridgeport Hospital will further audit time of accession to time of final result for specimens obtained from Bridgeport Hospital patients and processed at Yale School of Medicine to ensure continuity of service. Both of these metrics will be reported at the Laboratory Quality Committee. All results of specimens processed and read at Yale School of Medicine will be available for interpretation by ordering physicians at Bridgeport Hospital in the same manner as when specimens were processed at Bridgeport Hospital.	
		The "Significant Correction of Laboratory Results" Policy was revised on 8/21/18 to include a section for "Anatomic Pathology"  Pathologist were re-educated at the Laboratory Quality Assurance Committee on 9/5/18 on the need to issue amended reports if there is a change in diagnosis.  When a change in diagnosis is identified the Chairman of Pathology will be responsible to ensure amended reports are issued.	
8-9	2K	As of midnight 10/20/18 cytopathology specimens including GYN and non-GYN are no longer being processed at Bridgeport Hospital. Specimen processing will be done at Yale School of Medicine. As of 5:00 pm 10/22/18 interpretation of slides was discontinued at Bridgeport Hospital. Bridgeport Hospital will still be performing adequacy assessment for Non-GYN FNAs on site. These will be reconfirmed at Yale School of Medicine.	10/22/18
		Bridgeport Hospital has developed a memorandum of understanding with Yale School of Medicine to process and read all GYN and non-GYN cytopathology specimens. As part of this process, Bridgeport Hospital will ensure the quality of service provided by Yale School of Medicine by having Bridgeport-based	

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		pathologists review 20 percent of specimen slides originating at Bridgeport Hospital and then processed and interpreted at Yale School of Medicine. Bridgeport Hospital will further audit time of accession to time of final result for specimens obtained from Bridgeport Hospital patients and processed at Yale School of Medicine to ensure continuity of service. Both of these metrics will be reported at the Laboratory Quality Committee. All results of specimens processed and read at Yale School of Medicine will be available for interpretation by ordering physicians at Bridgeport Hospital in the same manner as when specimens were processed at Bridgeport Hospital.  The GYN SurePath policy had been updated to include a statement specific to the proper orientation of samples throughout processing & staining as per the manufacturer's instructions. In addition, chain of custody is criteria listed on the Cyto-Preparation Technician competency form.  (Responsible: Laboratory Medical Director)	
9	2L	As of midnight 10/20/18 cytopathology specimens including GYN and non-GYN are no longer being processed at Bridgeport Hospital. Specimen processing will be done at Yale School of Medicine. As of 5:00 pm 10/22/18 interpretation of slides was discontinued at Bridgeport Hospital. Bridgeport Hospital will still be performing adequacy assessment for Non-GYN FNAs on site. These will be reconfirmed at Yale School of Medicine.	10/22/18
		Bridgeport Hospital has developed a memorandum of understanding with Yale School of Medicine to process and read all GYN and non-GYN cytopathology specimens. As part of this process, Bridgeport Hospital will ensure the quality of service provided by Yale School of Medicine by having Bridgeport-based pathologists review 20 percent of specimen slides originating at Bridgeport Hospital and then processed and interpreted at Yale School of Medicine. Bridgeport Hospital will further audit time of accession to time of final result for specimens obtained from Bridgeport Hospital patients and processed at Yale School of Medicine to ensure continuity of service. Both of these metrics will be reported at the Laboratory Quality Committee. All results of specimens processed and read at Yale School of Medicine will be available for interpretation by ordering physicians at Bridgeport Hospital in the same manner as when specimens were processed at Bridgeport Hospital.	
		Utilizing the SurePath protocol for processing urines was discontinued and the process had reverted back to using the standard Cytospin process.	
9-10	2M	As of midnight 10/20/18 cytopathology specimens including GYN and non-GYN are no longer being processed at Bridgeport Hospital. Specimen processing will be done at Yale School of Medicine. As of 5:00 pm 10/22/18 interpretation of slides was discontinued at Bridgeport Hospital. Bridgeport Hospital will still be performing adequacy assessment for Non-GYN FNAs on site. These will be reconfirmed at Yale School of Medicine.	10/22/18

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Bridgeport Hospital has developed a memorandum of understanding with Yale School of Medicine to process and read all GYN and non-GYN cytopathology specimens. As part of this process, Bridgeport Hospital will ensure the quality of service provided by Yale School of Medicine by having Bridgeport-based pathologists review 20 percent of specimen slides originating at Bridgeport Hospital and then processed and interpreted at Yale School of Medicine. Bridgeport Hospital will further audit time of accession to time of final result for specimens obtained from Bridgeport Hospital patients and processed at Yale School of Medicine to ensure continuity of service. Both of these metrics will be reported at the Laboratory Quality Committee. All results of specimens processed and read at Yale School of Medicine will be available for interpretation by ordering physicians at Bridgeport Hospital in the same manner as when specimens were processed at Bridgeport Hospital.

The "Bridgeport Hospital Laboratory 2018 Quality Assurance and Process Improvement Plan and 2017 Evaluation" was amended to include a cytology section describing the incident where specimens were switched during processing and the corrective actions that were put into place. The indicators for 2018 to monitor compliance were also added. Review and approval was made at the 9/5/18 Laboratory Quality Assurance Committee. (Responsible: Laboratory Administrative Manager)

The nonconforming events log and minutes from the Laboratory Quality Assurance Committee from the prior year will be cross referenced to ensure the annual Quality Assurance and Process Improvement Plan being developed is comprehensive. (Responsible: Laboratory Administrative Manager)

The incident of the switched pathology slides was reviewed and discussed by the Vice President of Performance Improvement and Risk Management at the Professional and Quality Review Committee of the Board in September 2017. The Laboratory Department made a report to the Hospital's Quality Council (9/13/18) and the Professional and Quality Review Committee of the Board (9/20/18). The report included an update on the event and status of corrective actions and monitoring. The Laboratory Department is scheduled to report out at both committees twice per year. (Responsible: V.P. Ambulatory Services & Chairman of Pathology)

Ryan O'Connell, MD, Vice President, Performance and Risk Management October 31, 2018

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